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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/706,542 | 11/12/2003 | Linda S. Powers | 13368.0001 (DIV. II) | 6889 |
| 7590 | 10/05/2005 | | | |
| K. S. Cornaby Suite 1500 170 South Main Street Salt Lake City, UT 84101-1644 | | | | |
| | | | EXAMINER LUCAS, ZACHARIAH | |
| | | | ART UNIT 1648 | PAPER NUMBER |

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|-------------------------------|--|
| Office Action Summary | Application No. 10/706,542 | Applicant(s) POWERS ET AL. | |
| | Examiner Zachariah Lucas | Art Unit 1648 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 4-7,9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,8 and 10-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 1-13 are pending in the application.
2. In the prior action, mailed on April 7, 2005, claims 1-3, 8, and 10-13 were under consideration and rejected; and claims 4-7 and 9 were withdrawn as to non-elected inventions. In the Response submitted on August 31, 2005, the Applicant amended claims 1 and 3.
3. Currently, claims 1-3, 8, and 10-13 are under consideration.

Specification

4. Applicants claim for priority to prior application 09/999159 is noted. In the prior application, it was requested that the Applicant amend the specification to reflect that fact that the prior application 09/999159 has been issued as patent number 6,780,602. It is noted that the specification has been so amended.

Claim Rejections - 35 USC § 102

5. **(Prior Rejection- Withdrawn)** Claims 1 and 10-12 were rejected under 35 U.S.C. 102(b) as being anticipated by Piran et al. (U.S. 5,705,338). The Applicant has amended the claims such that they now require that the ligand tethered to the substrate is a peptide specific for an outer membrane protein, and such that the separation step is conducted through separation of the solution from the substrate with the tethered ligand bound to the analyte. In view of the amendment, and Applicant's arguments in accordance thereto, the rejection is withdrawn.

Claim Rejections - 35 USC § 103

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6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. **(Prior Rejection- Withdrawn)** Claims 1, 3, and 10-12 were rejected under 35 U.S.C. 103(a) as being unpatentable over Piran as applied to claims 1 and 10-12 above. The rejection is withdrawn for substantially the same reasons as indicated with respect to the rejection under 35 U.S.C. 102(b) over this rejection above.

8. **(Prior Rejection- Maintained)** Claims 2 and 8 were rejected under 35 U.S.C. 103(a) as being unpatentable over Piran as applied to claims 1, 3, and 10-12 above, and further in view of Powers et al. (WO 98/49557). In view of the amendment of claims 1, 3, and 10-12, and the fact that the teachings of Powers are required to teach the additional limitations of these claims, this rejection is extended such that claims 1-3, 8, and 10-12 are now rejected over the teachings of Piran in view of Powers.

The Applicant traverses this rejection on the basis indicated above. However, with respect to the present rejection, it is noted that it would have been obvious to those in the art to substitute the use of the ligands disclosed in the Powers reference for those in the Piran reference as was described in the prior action. It is additionally noted that the Powers reference also teaches the use of certain tethers for the attachment of the ligands to a substrate. It would therefore have also been obvious to those of ordinary skill in the art to use the substrates and

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ligands disclosed by the Powers reference in the methods disclosed by Piran. However, it is noted that the Applicant also provides additional arguments directed to the teachings of the Powers reference.

With respect to the additional teachings of the Powers reference, the Applicant asserts that there are two elements of the claimed rejection not disclosed by the Powers reference. First, the Applicant notes that the Powers reference does not teach steps of separating the substrate from the solution or (optionally) of washing away the unbound portions of the solution. However, the reference is teaching a binding assay. It is well known in the art for those in the art conducting a binding assay to include a washing step for the removal of non-bound analytes. See e.g., Fodor, columns 16-17. See also, U.S. 5,935,804, columns 33-34; U.S. 5,817,461, column 37; and U.S. 4,271,140, column 9 (each disclosing binding assays in which unbound materials are washed from the target analyte and ligand conjugates). Further, because the Powers method relies on the ability to detect the fluorescence of bound analyte, it would have been apparent to those in the art that unbound interfering materials would have to be removed prior to the detection step. Thus, based on the knowledge in the art, and the requirements of the method disclosed by Powers, it would have been obvious to those skilled in the art to include a washing step in the binding assay disclosed by Powers. The Applicant's assertion that Powers does not teach such a step is therefore not found persuasive in avoiding the obviousness rejection.

The Applicant next argues that the Powers reference does not teach the asserted tether lengths that are to be used for each analyte to be captured. In particular, the Applicant appears to be arguing that the presently claimed tether length would not have been the obvious optimized length. The Response argues that 40 is a non-obvious optimized length for "intact

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microorganisms” (page 9); but, not for other macromolecules such as proteins (Page 10, stating “We have not observed any improvements in binding of macromolecules (unlike microorganisms) when the tether length exceeds 20 .”). However, while the Applicant appears to be referring to teachings supporting their argument, the teachings are themselves insufficient absent presentation in the form of factual evidence. As is, the information is provided only in the form of attorney argument. Attorney argument is not an acceptable replacement for factual evidence. See e.g., MPEP 2145 I. It is suggested that a copy of the declaration filed in the parent application, from which the information described by the attorney appears to have been drawn, be submitted in the present application.

However, even upon submission of the data in the declaration, it is noted that the information argued by the Applicant is directed to the attachment of microorganisms such a bacteria to a substrate. The present claims are directed not to the binding of bacteria, but to the binding of viruses. The Applicant also argues that the optimum length of the tether varies with the size of the target analyte. See e.g., Response, page 9-10. It is known in the art that viruses take on a variety of sizes and shapes. See e.g., Lodish et al., Molecular Cell Biology, pages 202-12, esp., page 208, right column. The Applicant has not demonstrated that 40 represents the optimum tether length for any virus, or identify what viruses this length may represent an optimum length for capturing. Further, the art generally recognizes that viruses are smaller than the cells, thereby further indicating that the preferred tether length for a bacteria would not necessarily be the same for a virus. Thus, assuming that the Applicant submits a declaration provided the teachings referred to in the response, it is not clear that these teachings would be sufficient to demonstrate the non-obviousness of the currently elected invention, which is drawn

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to the capture of a different target than was identified in the referenced declaration. At the very least, the teachings of such a declaration do not appear as though they are commensurate with the scope of what is being claimed in that they are directed to the optimum performance of a different target analyte than that which was elected and is under examination in the present application. It is therefore not clear that any unexpected results that would be achieved in instances where the target is a bacterial cell would also be achieved where the target is, as in the present case, a virus.

Furthermore, it is noted that, while claim 2 (with respect to the elected embodiment) is limited to embodiments wherein the analyte is a virus, the remaining claims are not so limited. Thus, even if the Applicant does demonstrate that the unexpected results of using tethers of around 40 may be found with respect to both viruses and bacteria, claims 1, 3, 8, and 10-13 would still not be commensurate in scope with the unexpected results as they are directed to the detection of any analyte. The Applicant has asserted that the optimum length of the tether varies with the target analyte. Thus, use of the claimed method to detect other analytes than viruses and bacteria may or may not have the unexpected results. In particular, there is nothing in the claims to exclude the detection of protein analytes, which the application discloses as having an optimum tether length of significantly below 40.

For each of these reasons, this second argument, asserting unexpected results in the length of the tethers, is therefore not found persuasive. For these reasons, and for the reasons of record, the rejection is maintained.

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(Prior Rejection- Withdrawn) Claims 1-3, and 10-13 are rejected under 35 U.S.C.

103(a) as being unpatentable over Rothschild et al. (U.S. 5,948,624). In view of the amendments to the claims as described above, and the Applicant's arguments pursuant thereto, the rejection is withdrawn.

9. **(Prior Rejection- Restated as Necessitated by Amendment and Maintained)** Claims 1-3, 8, and 10-13 were rejected under 35 U.S.C. 103(a) as being unpatentable over Rothschild in view of Powers (supra). The claims have been amended as described above. In view of the amendments, the rejection is restated as a rejection of claims 1-3, 8, and 10-13 over the teachings of Powers in view of Rothschild. The teachings of the two references have been previously described, at least in part.

Powers teaches the use of non-antibody ligands tethered to a substrate for the capture of target analytes. It is noted that the tethers used in the Powers reference are identical to the photostable linkers disclosed in the present application. Cf., pages 20-23 of Powers, with pages 19-22 of the current application.

Rothschild teaches methods known in the art for the detection and identification of analytes, See e.g., Columns 8, and 12-15. While, as the Applicant notes, the Rothschild reference teaches a methods wherein ligands are attached to a substrate through photocleavable linkers in (e.g.) column 10 of the reference. However, this is an alternative embodiment, and does not constitute a teaching away from the use of the substrate and tethers of Powers in the general methods disclosed in the reference. It would therefore have been obvious to those in the art to substitute the substrate of Powers into the methods for detection and identification of analytes

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disclosed in Rothschild so as to take advantage of the benefits of the substrate and ligands disclosed by Powers. See e.g., Powers, pages 5 and 9-11. The combined teachings of the reference therefore render obvious the claimed invention for the reasons above, and the reasons of record.

The Applicant traverses the original rejection on substantially similar grounds to those asserted with respect to the rejection over Piran in view of Powers above. Those arguments are not found persuasive for the reasons discussed above.

In addition to those arguments, the Applicant also asserts that the teachings of the Rothschild reference teaches the use of photocleavable linkers in the disclosed methods, and asserts that the presently claimed methods are directed to the use of photostable tethers. However, as indicated above, the Powers reference teaches the use of the same tethers described in the present application. In view of these teachings of Powers, because the combination of the references renders obvious the use of the substrates and ligands of Powers in the general methods disclosed by Rothschild, and because the teachings of Rothschild with reference to photocleavable tethers is an alternative method to others disclosed in the reference and does not teach away from the claimed method, this argument is not found persuasive.

For these reasons, and for the reasons above and of record, the rejection is maintained.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. **(Prior Rejection- Maintained)** Claims 1, 2, 8, and 10-13 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 6, 9-23, 27, and 31-41 of U.S. Patent No. 6,780,602. No arguments have been presented in traversal of the rejection.

It is noted that claim 1 has been amended as described above. However, the additional limitations provided in the amended claims are achieved by the method taught by the claims of the reference. The rejection is therefore maintained.

12. **(Prior Rejection- Withdrawn)** Claim 1, 2, 4, 10-13 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of copending Application No. 10/706,543. It is noted that the claims of the copending application have been amended such that they now read only on methods for the identification of proteins contained within a microbe. As the present claims, and the elected embodiments of the claims, do not read on such an embodiment, the rejection is withdrawn.

13. **(Prior Rejection- Maintained)** Claims 1, 2, 8, 10-13 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over

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claim 21 copending Application No. 10/706,547. No arguments have been presented in traversal of the rejection. It is therefore maintained.

Conclusion

14. No claims are allowed.

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

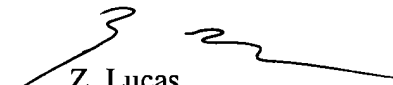
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Z. Lucas
Patent Examiner



JAMES HOUSEL 10/3/05
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